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Choose a different path.

Nasal polyp reduction with the SINUVA™ sinus implant

SINUVA™ (mometasone furoate) sinus implant: In-office CRSwNP implantable treatment

Key benefits:

- Localized drug delivery directly to the area of the nasal polyps minimizing the reliance on patient compliance
- Self-expanding bioabsorbable design[1]
- Continuous delivery of mometasone furoate for up to 90 days[1]
- Only FDA-approved implantable device for the treatment of nasal polyps

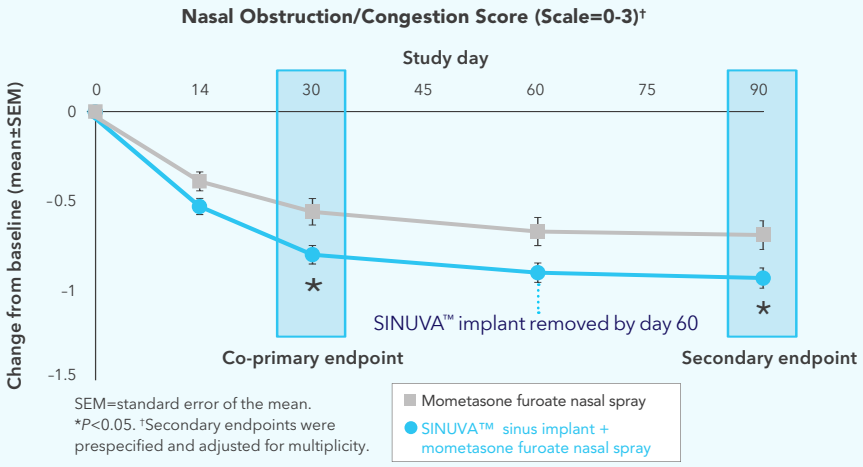
RESOLVE II (n=300): Co-primary efficacy outcomes[†,‡,1,2]

2.3 fold improvement in bilateral polyp grade from baseline to day 90 compared to once daily mometasone furoate nasal spray alone

Change from Baseline, Mean (SD) for SINUVA –0.56 (1.06) vs –0.15 (0.91) with mometasone furoate nasal spray alone (*P*=0.0073)

41% relative improvement in nasal obstruction/ congestion score from baseline to day 30 compared to once daily mometasone furoate nasal spray alone

Change from Baseline, Mean (SD) for SINUVA –0.80 (0.73) vs –0.56 (0.62) with mometasone furoate nasal spray alone (*P*=0.0074)



SEM=standard error of the mean.
**P*<0.05. †Secondary endpoints were prespecified and adjusted for multiplicity.

SINUVA™ sinus implants delivered improvement in nasal obstruction/ congestion at Day 30 and up to 90 days of sustained symptom relief.

Study design: The RESOLVE II study was a randomized, controlled, double-blind, multicenter study with 300 patients. Patients were ≥ 18 years of age with chronic rhinosinusitis who had prior bilateral total ethmoidectomy, but were indicated for revision endoscopic surgery because they presented with moderate to severe nasal obstruction/congestion symptoms and recurrent bilateral sinus obstruction due to sinonasal polyposis despite the use of intranasal corticosteroid sprays and recent high dose steroids. 201 patients were randomized to the SINUVA™ sinus implant treatment arm where they underwent bilateral placement of SINUVA™ sinus implant in the ethmoid sinuses. 99 patients were randomized to the control arm where they received a sham procedure. Patients in both study arms received once daily mometasone furoate nasal spray (200 µg) through Day 90.[1,2]

SD, standard deviation.
† **Co-primary endpoints:** Change from baseline to Day 90 in bilateral polyp grade, as determined by an independent panel on a scale of 0 (no visible nasal polyps) to 4 (nasal polyps completely obstructing nasal cavity). Change from baseline to Day 30 in nasal obstruction/congestion score, as determined by patients on a scale of 0 (no symptoms) to 3 (severe symptoms).[1]

INDICATION

SINUVA™ sinus implant is a corticosteroid-eluting implant indicated for the treatment of chronic rhinosinusitis with nasal polyps in adult patients > 18 years of age who have prior ethmoid surgery.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Patients with known hypersensitivity to mometasone furoate and any of the ingredients of the SINUVA™ sinus implant.

Please see additional important safety information on the following page.

RESOLVE II: Secondary efficacy outcomes (baseline to Day 90)[2]

	SINUVA™ sinus implant (n=201)	Control (Mometasone furoate nasal spray) (n=99)	*p*-value
Indicated for repeat surgery % Reduction from baseline	61%	37%	0.0004
Nasal obstruction/congestion score Mean change from baseline (SD)	-0.93 (0.80)	-0.69 (0.79)	0.0248
Ethmoid sinus obstruction Mean change from baseline (SD)	-11.3 (18.1)	-1.9 (14.4)	0.0007
Sense of smell Mean change from baseline (SD)	-1.20 (1.66)	-0.76 (1.60)	0.0470

Patients treated with SINUVA™ (mometasone furoate) sinus implant did not experience a significant improvement in their self-reported facial pain/pressure score.
The mean change (SD) for SINUVA™ sinus implant was –0.77 (1.21) vs –0.90 (1.27) with control (*P*=0.9130).

The RESOLVE II study was a randomized, controlled, double-blind, multicenter study with 300 patients.

Secondary endpoints: Proportion of patients still indicated for repeat ESS at Day 90 despite ongoing intranasal steroid use based on clinical investigator assessment using study-specific criteria. Change from baseline to Day 90 in nasal obstruction/congestion score, as determined by patients on a scale of 0 (no symptoms) to 3 (severe symptoms). Change in percent ethmoid sinus obstruction at Day 90, as determined by the independent, blinded panel on a 100-mm visual analogue scale (VAS). Decreased sense of smell and facial pain/pressure score change from baseline to Day 90, as determined by patients on a six point Likert scale of 0 (absent) to 5 (very severe). *P*-values for secondary endpoints were prespecified and adjusted for multiplicity.[2]

INDICATION

SINUVA Sinus Implant is a corticosteroid-eluting implant indicated for the treatment of chronic rhinosinusitis with nasal polyps in adult patients ≥ 18 years of age who have had ethmoid sinus surgery.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Patients with known hypersensitivity to mometasone furoate and any of the ingredients of the SINUVA Sinus Implant.

WARNINGS AND PRECAUTIONS

Local Nasal Adverse Reactions: Monitor nasal mucosa adjacent to the SINUVA Sinus Implant for any signs of bleeding (epistaxis), irritation, infection, or perforation. Avoid use in patients with nasal ulcers or trauma.

Glaucoma and Cataracts: Nasal steroids may result in development of glaucoma and/or cataracts. Glaucoma, cataracts, and clinically significant elevation of intraocular pressure were not observed in patients from the treatment group of one randomized controlled clinical study (N = 53) who underwent bilateral placement of SINUVA Sinus Implants. Close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.

Hypersensitivity Reactions: Hypersensitivity reactions, including rash, pruritus, and angioedema have been reported with the use of corticosteroids.

Immunosuppression and Risk of Infections: Persons who are using drugs that suppress the immune system, such as corticosteroids, including SINUVA Sinus Implant are more susceptible to infections than healthy individuals. The safety and effectiveness of SINUVA Sinus Implant have not been established in pediatric patients less than 18 years of age and SINUVA is not indicated for use in this population. Corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infection of the respiratory tract; untreated systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.

Hypercorticism and Adrenal Suppression: If corticosteroid effects such as hypercorticism and adrenal suppression appear in patients, consider sinus implant removal.

ADVERSE REACTIONS

The most common adverse reactions observed (> 1% of subjects) in clinical studies were asthma, headache, epistaxis, presyncope, bronchitis, otitis media, and nasopharyngitis.

POSTMARKETING EXPERIENCE

The following adverse reactions have been identified during post-approval use of the SINUVA sinus implant. These events include implant migration, lack of efficacy, nasal pain, headache, epistaxis.

Rx only. Please see Full Prescribing Information for SINUVA attached to this document and available at **SINUVA.com/hcp.**

References:
‡ Improvement calcuated in post-hoc analysis as [(T-C)/C] *100 using values reported in the SINUVA prescribing information and Kern (2018).
1. SINUVA [Prescribing Information]. Menlo Park, CA: Intersect ENT; 2023.
2. Kern RC, Stolovitzky JP, Silvers SL, et al. A phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps. *Int Forum Allergy Rhinol*. 2018;8(4):471-481.

SINUVA™ (mometasone furoate) sinus implant
RX only. Please see full accompanying prescribing information at **SINUVA.com/PI**

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